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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,093	12/17/2003	Richard E. Stein	13569.82USI1	3171

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EXAMINER	
FAULCON JR, LENWOOD	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,093	STEIN ET AL.	
	Examiner	Art Unit	
	Lenwood Faulcon, Jr.	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton et al. (U.S. Patent No. 6,249,703) in view of Nappholz et al. (U.S. Patent No. 5,720,770).

Stanton et al. teaches of a handheld patient programmer/monitor for an implanted medical device, which comprises a plurality of light-emitting diodes and an audible beeper for providing tactile, audible and visual feedback to the user of the programmer and implanted device (col. 4 lines 41-48). Stanton et al. further teaches of the handheld patient programmer communicating with the implanted device by telemetry (col. 6 lines 63-67 and col. 7 lines 1-17). Stanton el al. also teaches of a self-contained power supply (col. 7 lines 23-27).

Nappholz et al. teaches of a cardiac system with enhanced communication and control capability, which comprises an implantable cardiac monitoring and/or stimulation device and an external device which is more specifically a repeater programmer and telephone (col. 3 lines 61-65). Nappholz et al. also teaches that the external unit is a portable unit designed to provide comprehensive continuous or intermittent two way communication between the implanted device over a RF link (col. 10 lines 37-47). It is

inherent that the portable external unit that is taught by Nappholz et al. is capable of fitting in the grasp of a user's hand. Nappholz et al. further teaches of using a voice message to communicate to the patient that an atrial fibrillation has been detected and that a device has switched to a new mode of operation (col. 9 lines 53-66). Nappholz et al. also teaches that the external controller performs a protocol at regular intervals to collect information pertaining to the patient, current operational parameters and other data (col. 8 lines 10-33).

It would have been obvious to one having ordinary skill in the art to combine the teachings of Stanton et al. and Nappholz et al. to have an external controller for an implantable stimulation device that has audible and visual feedback indicators. Stanton et al. and Nappholz et al. both teach of implantable stimulation devices with external controllers that have monitoring and feedback capabilities, and thus teach of analogous arts. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Stanton et al. to have the device work in conjunction with an implantable cardiac stimulating device such as the device as taught by Nappholz et al., since Stanton et al. teaches of a patient programmer that controls an implanted medical device (col. 4 lines 20-23), which is interpreted to include implanted cardiac stimulating devices. It would have been obvious to one having ordinary skill in the art to modify the system as taught by Stanton et al. to include information relating to the patient's condition in the feedback gathered by the external controller, since this type of feed back is commonly indicated by controllers and/or monitors for improved feedback as to the patient's condition, as taught by Nappholz et al.

It would have also been obvious to one having ordinary skill in the art to modify the system as taught by Stanton et al. to include voice signals as audible indicators as taught by Nappholz et al. to provide clear communication as to the condition of the patient or the system. It would have also been obvious to one having ordinary skill in the art at the time of the invention to modify the devices as taught by Stanton et al. and Nappholz et al. to monitor the patient's condition for various time intervals, including a forty-eight hour interval, if the physician deemed such an interval necessary to access the patient's condition. Further, it would have been obvious to one having ordinary skill in the art that the external unit as taught by Stanton et al. could be modified to use the visual and audible indicators in various embodiments in order to alert the patient of his or her physical condition, to suggest contacting a physician, and to further control the operation of the implanted device, since external programmer/monitor units are commonly known to work with implantable stimulation devices with various embodiments, as taught by Nappholz et al. (col. 1 lines 34-55, col. 7 lines 34-58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Stanton et al. with the teachings of Nappholz et al. to have the limitations of claims 1-6.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fischell (U.S. Patent No. 4,295,474), (U.S. Patent No. 5,674,249), Kaemmerer (U.S. Patent No. 5,693,076), (U.S. Patent No. 5,720,770), (U.S. Patent No. 6,057,758), (U.S. Patent No. 6,821,249).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lenwood Faulcon, Jr.

George Manuel

Primary Examiner